DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 30, 2014

Tria Beauty Incorporated
% Mr. Johnathan Kahan
Hogan Lovells US LLP
555 Thirteenth Street, North West
Washington, District of Columbia 20004

Re: K141868
Trade/Device Name: Tria FANp
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONG
Dated: November 12, 2014
Received: November 12, 2014

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141868

Device Name
Tria Fanp

Indications for Use *(Describe)*

The FANp is an over-the-counter device indicated for the treatment of periorbital wrinkles (crow's feet).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Tria Beauty's Tria FANp

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Tria Beauty, Inc.
4160 Dublin Blvd, Ste 200
Dublin, CA 94568
Phone: 925-452-2500
Facsimile: 925-452-2595
Contact Person: Tobin Island, Ph.D.
Date Prepared: June 30, 2014

Name of Device and Name/Address of Sponsor

Tria FANp
Tria Beauty, Inc.
4160 Dublin Blvd, Ste 200
Dublin, CA 94568

Common or Usual Name

Diode Laser

Classification Name

Laser Instrument, Surgical, Powered
Regulation Number: 21 CFR§878.4810
Product Code: ONG

Predicate Devices

Tria Beauty, Inc., Tria FAN System (K130459)

Intended Use / Indications for Use

Tria FANp is an over-the-counter device indicated for the treatment of periorbital wrinkles (crow's feet).

Technological Characteristics

The Tria FANp is a semiconductor diode laser system that delivers infrared light at a wavelength of 1450 nm ± 50 nm.

Performance Data

Performance data was submitted with this 510(k) notification to support the determination of substantial equivalence for the Tria FANp relative to its predicate device.

Performance Testing (Non-Clinical):

Performance testing was conducted to demonstrate that the Tria FANp performs according to specifications and functions as intended.

Animal:

A GLP compliant histology study was conducted. Hairless guinea pigs were treated with the Tria FANp and tissue sampling occurred immediately, 5 days, and 14 days post-treatment. The tissue response was found to be equivalent to the predicate non-ablative fractional device.

Clinical:

A 45-subject, prospective, open-label safety and effectiveness study was conducted to evaluate the Tria FANp for the treatment of periorbital wrinkles. The Tria FANp was found to be as safe and effective as the predicate non-ablative fractional device.

Substantial Equivalence

The Tria FANp has the same intended use and indication, the same principles of operation, and similar technological characteristics as its predicate device. The minor technological differences between the Tria FANp and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Tria FANp is as safe and effective as the predicate device. Thus, the Tria FANp is substantially equivalent.